Claims 15, 16, 18-20, and 29-30 have been amended to more clearly set forth the subject matter being claimed. The amendment is supported by the original disclosure. For example, the text of the original specification at page 11, line 30 through page 13, line 16 (or the substitute specification filed with this Rule 60 application on May 26, 1993, at page 14, line 3 through page 16, line 4), discusses each of the recited proteins, the purification procedures, and that antibodies bind with these proteins. Further support can be found in the original specification at page 9, line 32 through page 10, line 29 (and in the substitute specification at page 11, line 17 through page 12, line 21) where immunocomplexes, labelled proteins, and immunoassays are discussed. Finally, original claims 1 and 7 recite antibodies to HIV-1 (LAV) proteins and immunological complexes formed by the antibodies and proteins. Thus, the claims as amended are supported in the original disclosure and no new matter enters by this amendment.

Applicants acknowledge the withdrawal of the rejection under 36 U.S.C. § 102(a).

In the Advisory Action mailed November 15, 1994, the Examiner maintained the rejection to claims 29-31 under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. This rejection is respectfully traversed.

The Examiner stated that "the disclosed utility is directed to detecting the presence of anti-HIV antibodies" and that "the claimed complexes have no utility of themselves." Advisory Action at page 2. Under the Guidelines for Examination of Applications

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for Compliance With the Utility Requirement (Utility Guidelines), Fed. Reg., vol. 60, No. 1, January 3, 1995, page 98, the Examiner must consider utilities that would be considered by one of ordinary skill in the art and not only a disclosed utility. Furthermore, the standard the Examiner has applied in this case for the utility requirement is inappropriate. This will be made clear below.

The specification clearly indicates that immunological methods for detecting antibodies to proteins of HIV-1 are included in the applicants' invention. Substitute specification at page 7. One of ordinary skill in the art is clearly aware that such immunological methods involve the formation of an immune complex. Such knowledge is well known. Whether or not applicants' specification specifically discusses the utility of immune complexes, one of ordinary skill in the art would recognize that immune complexes are necessary parts of many immunological methods. Therefore, one of ordinary skill in the art would know that immune complexes are useful compositions.

Under the Utility Guidelines, if a "use would be readily apparent to a person of ordinary skill in the art, the Examiner should not impose a rejection under section 101." Fed. Reg., vol. 60, No. 1 at 98. In this case, as shown above and set forth in the Amendment and Exhibits filed October 11, 1994 (see pages 4-7 and Exhibits 1-2), one of ordinary skill in the art would readily see the utility of the claimed invention of claims 29-31. Therefore, this rejection is in error and applicants respectfully request its withdrawal.

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In addition, applicants do not understand the contention that immune complexes "have no utility of themselves." The same could be said of nearly any article of manufacture or composition. For example, a sparkplug would have no utility absent a combustion engine and battery. Of course, the utility of a composition must be considered in the context of the art and how one of ordinary skill in the art views it. Since one of ordinary skill in the art recognizes an immune complex as a necessary, valuable part of many immunological methods, immune complexes have a recognized utility in the art.

Furthermore, the decision of In re Irani, 487 F.2d 924, 180 U.S.P.Q. 44 (C.C.P.A. 1973), should not be construed as limiting utility to chemical intermediates which undergo a change (see Office action of July 12, 1994, at page 4). Just as a catalyst is not changed by the process of a reaction but is still useful, an immune complex is also useful. Thus, whether or not a compound is changed by a reaction it participates in does not in itself control the issue of usefulness of that compound.

Finally, the Federal Circuit recently stated that "usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." In re Brana, 34 U.S.P.Q.2d 1437, 1442 (Fed Cir. 1995). In this case, it is not appropriate to limit consideration of patentable utility as the Examiner has done. One of skill in the art would have a clear understanding that an immune complex can be manipulated into numerous practical assays.

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It is that understanding, *inter alia*, that supports the utility for the claimed invention of claims 29-31.

This rejection is in error and applicants respectfully request its withdrawal.

The specification is objected to and claims 15, 16, 18-20, and 29-31 are rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly fails to adequately teach how to make and/or use the invention. This objection and rejection are respectfully traversed.

At pages 3-4 of the Advisory Action, the Examiner responds to applicants' arguments and citations to the specification, but concludes that the specification nowhere teaches "the isolation and purification of complexes or the purification of antigens or antibodies from complexes." Advisory Action at page 4.

All of the pending claims have been amended to more clearly set forth the subject matter being claimed. Applicants submit that the specification does indeed teach how to make and use the claimed invention, and that such teaching is clear from the Examiner's observations and the knowledge of one of ordinary skill in the art.

The Examiner remarks at page 3 that "Pages 10 and 11 show that immune complexes are the result of the interaction of radiolabelled proteins with antibodies found in sera from infected individuals." Thus, the specification clearly identifies and teaches that immune complexes are formed from the reaction of the disclosed proteins. Furthermore, the purification of the proteins recited in the claims is set forth at page 12, lines 1-37 of the

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original specification. With the isolated and purified protein, all of the claims reciting antibodies and immune complexes which bind to or formed with those proteins are enabled to one of skill in the art.

At page 4 of the Advisory Action, there is a comment that "nowhere does the specification teach ... the purification of antigens...." As noted above, the original specification does indeed disclose the purification of the recited proteins. The methods referred to there, specifically citing Montelaro et al. (1982) (copy enclosed for the Examiner's convenience), may be used for the isolation and purification of the recited proteins as is plainly stated in the original specification.

The Patent Office bears a heavy burden in contradicting statements of enablement and description in an applicant's disclosure. As recently restated by the Federal Circuit in In re Brana, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), such a disclosure "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements therein which must be relied on for enabling support." *citing* In re Marzocchi, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

In this case, there is no reason to doubt the objective truth of the applicants' statements in the specification. Therefore, the amended claims are indeed enabled by the original disclosure and applicants respectfully request the withdrawal of this rejection and this objection.

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Applicants' specifically traverse the comment at page 4 of the Advisory Action that the use of monoclonal antibodies is not enabled by the specification. Since the procedure for making monoclonal antibodies was well known at the time the invention was made (Kohler and Milstein published the first work a decade earlier), applicants' disclosure of the HIV-1 antigens recited in the claims, as well as their isolation, would enable one of skill in the art to produce monoclonal antibodies. This is also clear form the exhibits filed with the Amendment of October 11, 1994, showing how to make monoclonal antibodies that bind to proteins. Therefore, one of skill in the art would have been enabled to produce monoclonal antibodies to the recited proteins.

For the above reasons, this objection and rejection are in error and applicants respectfully request their withdrawal.

Claims 15-21 and 32-36 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Barre-Sinoussi et al. (Barre-Sinoussi). This rejection is respectfully traversed.

Initially, applicants note that rejected claims 17, 21, and 32-36 were cancelled without prejudice or disclaimer in the Amendment filed October 11, 1994. Thus, the rejection to these claims is moot.

Second, applicants note that the rejection under 35 U.S.C. § 102(a) has been withdrawn. Therefore, any "reasons" for this rejection based upon that withdrawn rejection, as mentioned at page 4 of the Advisory Action, do not appear relevant.

In response to the comments in the Advisory Action, applicants submit that the Barre-Sinoussi document is not prior

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art for this application for three reasons. First, it has not been shown that the Barre-Sinoussi document was published before the originally filed application Serial No. 06/706,562, filed February 28, 1985, which this application is related to by continuation and divisional applications. Second, the Barre-Sinoussi abstract is not an enabling disclosure that could support a 35 U.S.C. § 103 rejection of the claims herein. Therefore, Barre-Sinoussi would not be prior art even if priority were not claimed to earlier-filed applications. And finally, the priority documents for this application predate the publication of Barre-Sinoussi and support the claimed invention. Applicants expand upon these three reasons below.

The Barre-Sinoussi document, on its face, is not "prior art" to this application since it was not published before applicants' original filing date in the U.S. The Abstract of Barre-Sinoussi, which is all that has been cited against this application, does not have a date on it. All the abstract says is "PY 1985," apparently representing "publication year 1985." However, there is nothing to indicate that the abstract was published prior to February 28, 1985. If the Examiner is relying on personal knowledge for the date of publication, applicants respectfully request an Examiner's Affidavit under 37 C.F.R. § 1.107(b) so applicants can properly respond to it.

In fact, the undersigned has been informed by the publishers of "Retroviruses And Human Pathology" (Humana Press), the text which includes the Barre-Sinoussi abstract, that the publication date of the Barre-Sinoussi chapter was April 8, 1986. Enclosed as

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Exhibit 1 is a copy of the copyright material available for "Retroviruses And Human Pathology" showing the date of publication as April 9, 1986. There is no indication anywhere that any abstract was available prior to that date of publication. Therefore, the Barre-Sinoussi abstract does not appear to be "prior art" for this application.

The second reason is that the text of the abstract itself does not enable the claimed invention herein and thus does not make the claimed invention obvious. The Barre-Sinoussi abstract nowhere states how to obtain the virus from which the proteins are derived. Without such information, one of skill in the art could not have produced the proteins as disclosed in applicants' specification in order to generate or identify antibodies which bind to them. Therefore, the Barre-Sinoussi abstract would not enable one of ordinary skill in the art to arrive at applicants' claimed invention.

The third reason that Barre-Sinoussi cannot support this 35 U.S.C. § 103 rejection is that applicants' foreign priority documents both support the claimed invention and predate even an alleged publication date of February 1985. In the Advisory Action at page 4, there is a contention that the isolation of particular proteins is irrelevant as support for the claimed invention. However, the amended claims are supported by the disclosure of priority documents at the previously indicated pages since the p15, p25, p36, p42, and p80 proteins are disclosed in GB 83 24800 and the South Africa application 84/7005 discloses the p12 in addition to all the other proteins recited in the claims. One of

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1300 I STREET, N. W.
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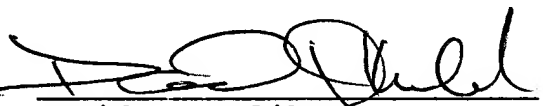
skill in the art, once isolating and purifying the recited proteins by the disclosed methods, could have used known techniques to make and use the claimed invention herein. Therefore, the priority documents support the claims as amended.

For these reasons, this rejection is in error and applicants respectfully request its withdrawal.

If there are any other fees due in connection with the filing of this submission, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER

By: 
David J. Kulik
Reg. No. 36,576

Dated: July 11, 1995

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